UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

FEDERAL TRADE COMMISSION, Plaintiff, v. NEORA, LLC, *et al.*, Defendants.	)	Civil Action No. 3:20-cv-01979-M

PLAINTIFF FEDERAL TRADE COMMISSION'S MOTION
TO EXCLUDE EXPERT TESTIMONY OF DR. MINDY KURZER

Plaintiff Federal Trade Commission ("FTC") moves the Court for an order excluding the testimony of Dr. Mindy S. Kurzer, an expert witness for Defendants Neora, LLC (formerly known as Nerium International, LLC) and Jeffrey Olson. Dr. Kurzer's report offers (1) no rebuttal to the testimony of the FTC's experts she responds to, (2) unreliable factual determinations that should be left to the Court, (3) irrelevant legal opinions on Food and Drug Administration ("FDA") rules, and (4) irrelevant opinions on claims not challenged by the FTC. Kurzer's opinions are inadmissible under Federal Rule of Evidence 702 because they are unreliable and irrelevant and will not assist the trier of fact. Fed. R. Evid. 702.

I. Background

Since at least 2014, Defendants have made unsupported health claims about eicosanoyl-5-hydroxytryptamide (EHT), a coffee extract, and products containing EHT ("EHT Products").[1] Specifically, Defendants have claimed that EHT and EHT Products can prevent, reduce the risk of, or treat concussions or chronic traumatic encephalopathy (CTE), Alzheimer's disease, and Parkinson's disease, and that these effects are established by scientific proof. Defendants disseminated these claims in print, online, on social media, and at live meetings and events. Through these means, as alleged in Counts III and IV of the FTC's Complaint, Defendants made unsubstantiated efficacy claims and false establishment claims about EHT and EHT Products and thereby violated Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

To support Counts III and IV of its Complaint, the FTC introduced reports from two experts in the relevant fields: (1) Dr. Charles Tator, Professor in the Department of Surgery at the University of Toronto, Emeritus Scientist at Krembil Research Institute, and Director of the

[1] Neora's EHT supplements, currently marketed as "Neora EHT," were formerly known as "Nerium EHT" before Neora, LLC changed its name from Nerium International, LLC.

Canadian Concussion Centre, who evaluated Defendants' claims related to concussions and CTE; and (2) Dr. James Mastrianni, Professor of Neurology and Director of The Center for Comprehensive Care and Research on Memory Disorders at the University of Chicago Pritzker School of Medicine, who evaluated Defendants' claims related to Alzheimer's and Parkinson's. Dkt. 148-1 at 292, 295, FTC MSJ App. 1120, 1123 (Tator Report ¶¶ 2, 16); Dkt. 148-1 at 250, 253, FTC MSJ App. 1078, 1081 (Mastrianni Report ¶¶ 2, 15). Both Dr. Tator and Dr. Mastrianni found that, to be substantiated, the challenged claims would require clinical trials with human subjects; specifically, randomized, placebo-controlled, double-blind human clinical trials. FTC MSJ App. 1125 (Tator Report ¶ 25); FTC MSJ App. 1084 (Mastrianni Report ¶ 23). Both experts also concluded that substantiating the claims would require testing the product itself, not just the EHT extract or other ingredients the product contains. FTC MSJ App. 1121, 1125 (Tator Report ¶¶ 6, 25); FTC MSJ App. 1081-82, 1084 (Mastrianni Report ¶¶ 14, 18, 23). Applying these standards, Dr. Tator concluded that there is no evidence to support the claims that EHT or EHT Products prevent or treat concussions or CTE, FTC MSJ App. 1125 (Tator Report ¶ 26), and Dr. Mastrianni concluded that there is no evidence to support the claims that EHT or EHT Products prevent or treat Alzheimer's or Parkinson's. FTC MSJ App. 1084 (Mastrianni Report ¶ 24).

In her report, Dr. Kurzer makes no attempt to rebut the conclusions reached by Drs. Tator and Mastrianni. *See* App. 32-34 (Kurzer Dep. 30:2 to 32:6). Instead, Dr. Kurzer argues that their conclusions are irrelevant because, in her view, Defendants never made the challenged claims about the effects of EHT and EHT products on concussions, CTE, Alzheimer's and Parkinson's. Dkt. 148-1 at 535, 537, FTC MSJ App. 1363, 1365 (Kurzer Report § II, IV.A.2.a). But the issue of whether Defendants made these claims is an issue of fact to be decided by the Court, not by Dr. Kurzer, and her opinion on this issue is well outside her personal knowledge and expertise.

Dr. Kurzer also contends that Defendants did not violate certain FDA rules (or guidance), but this case has nothing to do with such violations, and her opinion on FDA rules assumes, once again, that Defendants never made the challenged claims. FTC MSJ App. 1365-66 (Kurzer Report § IV.A.2.a & b). Finally, Dr. Kurzer opines that Defendants have adequate substantiation, not for the challenged claims about EHT and EHT products, but for certain other claims that are not at issue in this case, and are therefore wholly irrelevant. FTC MSJ App. 1368-78 (Kurzer Report §§ V & XI).

II. Legal Standards

Pursuant to Federal Rule of Evidence 702, the proponent of expert testimony bears the burden of proving that such testimony: (a) provides expertise that would be helpful to the trier of fact; (b) is based on sufficient facts or data; and (c) results from reliable principles and methods that (d) have been reliably applied to the facts of the case. Fed. R. Evid. 702; *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (burden of proof). Trial courts hold a "gatekeeping" function to ensure that expert testimony is admissible. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589, 592-93 (1993); *see Burleson v. Texas Dep't of Crim. Just.*, 393 F.3d 577, 583-84 (5th Cir. 2004).

The requirement that expert testimony be "helpful" to the trier of fact "goes primarily to relevance." *Daubert*, 509 U.S. at 591. "To be relevant, the expert's 'reasoning or methodology [must] be properly applied to the facts in issue.'" *Puga v. RCX Sols., Inc.*, 922 F.3d 285, 293 (5th Cir. 2019) (alteration in original) (quoting *Johnson v. Arkema, Inc.*, 685 F.3d 452, 459 (5th Cir. 2012)). To be reliable, expert testimony "must be more than unsupported speculation or subjective belief." *Curtis v. M&S Petroleum, Inc.*, 174 F.3d 661, 668 (5th Cir. 1999) (citing *Daubert*, 509 U.S. at 590). Further, "an expert may never render conclusions of law," *Goodman*

v. Harris Cnty., 571 F.3d 388, 399 (5th Cir. 2009), and an expert cannot "'make factual determinations reserved for the trier of fact.'" *Melendez v. S. Fid. Ins. Co.*, 502 F. Supp. 3d 1071, 1075 (E.D. La. 2020) (quoting *Highland Cap. Mgmt., L.P. v. Bank of Am., N.A.*, 574 F. App'x 486, 491 (5th Cir. 2014)).

III. Dr. Kurzer's Opinions Are Inadmissible Under Fed. R. Evid. 702 and *Daubert*.

Dr. Kurzer's testimony fails to meet the requirements of Fed. R. Evid. 702 and *Daubert* because she provides no relevant opinion testimony on matters at issue. First, Dr. Kurzer offers no opinion on whether Defendants had proper substantiation for the challenged claims about EHT and EHT products. This is the sole issue addressed by the FTC's experts, Drs. Tator and Mastrianni, but Dr. Kurzer provides no rebuttal to their testimony whatsoever. Second, Dr. Kurzer's opinion that Defendants never made the challenged claims in the first place is wholly unreliable and unhelpful to the Court for several independent reasons: she ignores substantial contrary evidence of record, omits any meaningful review of relevant marketing materials, fails to describe or apply any principle or method for interpreting advertising claims, and lacks expertise in advertising and marketing. Third, Dr. Kurzer's other opinions, about FDA rules and claims the FTC has not challenged, are irrelevant to the issues before the Court. In sum, Dr. Kurzer's testimony is unreliable and unhelpful to the Court on the matters at issue and should therefore be excluded.

A. Dr. Kurzer does not address substantiation for the challenged claims.

The principal reason for excluding Dr. Kurzer's testimony is that she completely fails to address the issue addressed by the FTC's experts, *i.e.*, whether Defendants have the requisite level of substantiation for claiming that EHT or EHT products prevent, reduce the risk of, or treat concussions, CTE, Alzheimer's or Parkinson's. In legal terms, this concerns the second of the

three elements that the FTC must establish to prove deception or false advertising under the FTC Act. The three elements are: (1) a representation that is (2) likely to mislead consumers acting reasonably under the circumstances and is (3) material. *In re Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 164-65, 1984 WL 565319, at *45 (1984); *accord FTC v. Nat'l Bus. Consultants, Inc.*, 781 F. Supp. 1136, 1142 (E.D. La. 1991)*; Sw. Sunsites, Inc. v. FTC*, 785 F.2d 1431, 1435 (9th Cir. 1986); *FTC v. Wellness Support Network, Inc.*, No. 10-cv-04879-JCS, 2014 WL 644749, at *10, 15-17 (N.D. Cal. Feb. 19, 2014). The FTC can meet its burden to prove the second element, that Defendants' advertising claims were likely to mislead consumers acting reasonably, by showing that Defendants lacked the requisite level of substantiation for the challenged claims. *Wellness Support Network*, 2014 WL 644749, at *15. This is the purpose for which the FTC introduced the testimony of Drs. Tator and Mastrianni, both of whom concluded that the challenged claims were unsubstantiated. FTC MSJ App. 1125 (Tator Report ¶ 26); FTC MSJ App. 1084 (Mastrianni Report ¶ 24).

In response, Dr. Kurzer simply contends that the FTC's experts "do not actually address the claims made by Neora, LLC." FTC MSJ App. 1363 (Kurzer Report § II). Dr. Kurzer acknowledges that Drs. Tator and Mastrianni evaluated the claims at issue in this case about concussions, CTE, Alzheimer's and Parkinson's, FTC MSJ App. 1364, 1367 (Kurzer Report §§ IV.A, A.1 & B), which is undeniable since both experts state explicitly in their reports that the FTC asked them to evaluate these very claims. FTC MSJ App. 1081, 1123 (Mastrianni Report ¶ 15; Tator Report ¶ 16): *see also* App. 54-55 (Kurzer Dep. 52:1 to 53:15). Yet Dr. Kurzer declines to evaluate the claims herself, based on her opinion that Defendants never made them. FTC MSJ App. 1363, 1365, 1367 (Kurzer Report § II, IV.A & B). In so doing, she observes that a Neora document listing research studies on EHT and other ingredients, which the FTC's

experts reviewed and attached to their reports, does not itself make any claims about concussions, CTE, Alzheimer's or Parkinson's. FTC MSJ App. 1364, 1368 (Kurzer Report § IV.A.1 & B). But this is irrelevant. Drs. Tator and Mastrianni are experts on neurological injuries and diseases, not advertising. FTC MSJ App. 1079, 1120 (Mastrianni Report ¶ 7; Tator Report ¶ 4). Their reports address only the substantiation necessary for the challenged claims, not whether Defendants made the claims; and this is entirely proper. *See, e.g., Wellness Support Network*, 2014 WL 644749, at *9 (finding that FTC's expert on substantiation was not required to verify that defendants made the advertising claims at issue). To establish that Defendants made the claims, the FTC has relied on other voluminous evidence cited in its Complaint and produced by both sides in discovery, as Defendants are fully aware.

Although Dr. Kurzer fails to address the issue of substantiation for the challenged claims, making her qualifications a moot point, she also lacks the necessary qualifications to offer expert opinion on whether Defendants have adequate substantiation for these claims. She admits that she is not an expert in concussions, CTE, Alzheimer's, Parkinson's, neurology, or neurodegenerative disease. App. 27 (Kurzer Dep. 25:2-16); *see also* App. 22-23 (Kurzer Dep. 20:6 to 21:4). Under the circumstances, she cannot offer relevant testimony on whether Defendants had the requisite level of substantiation to claim that their EHT products prevent or treat these medical conditions. Her testimony should therefore be excluded. *See Wilson v. Woods*, 163 F.3d 935, 937 (5th Cir. 1999) ("A district court should refuse to allow an expert witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject."); *Macy v. Whirlpool Corp.*, 613 F. App'x 340, 345 (5th Cir. 2015) ("We require that a witness's qualifying training or experience, and resultant specialized knowledge,

are *sufficiently related* to the issues and evidence before the trier of fact [such] that the witness's proposed testimony will help the trier of fact.") (cleaned up).

B. Dr. Kurzer's opinion on whether Defendants made the claims is unreliable.

Dr. Kurzer's opinion that Defendants never made any claims about concussions, CTE, Alzheimer's, or Parkinson's should likewise be excluded as unsupported and unreliable. She lacks personal knowledge about Defendants' marketing campaigns, and she reached her purported expert opinion about Defendants' claims without meeting any of the requirements under Fed. R. Evid. 702 and *Daubert*. Her testimony is inadmissible for several independent reasons.

First, Dr. Kurzer's opinion on what claims Defendants made is contrary to voluminous evidence of record showing that Defendants made the challenged claims in print, online, on social media, and at meetings and live events. *See* Dkt. 144 at 25-38. To be admissible under Fed. R. Evid. 702, expert testimony must be reliable and helpful to the Court. Dr. Kurzer cannot help the Court by expressing an opinion that simply ignores all this contrary evidence.

Second, Dr. Kurzer did not perform any meaningful review of Defendants' advertisements and marketing materials. Apart from a single website she visited, Dr. Kurzer does not identify or attach any marketing materials she reviewed or evaluated. FTC MSJ App. 1363, 1418 (Kurzer Report § II & App. E); *see also* App. 30, 51-53, 61-62 (Kurzer Dep. 28:14-25, 49:21 to 51:13, 59:6 to 60:21). At her deposition, moreover, Dr. Kurzer refused to identify any advertisements she may have reviewed with counsel. App. 55-57 (Kurzer Dep. 53:16 to 55:6). Under the circumstances, her opinion about whether Defendants made the challenged claims is unreliable and inadmissible. *See Paz v. Brush Engineered Materials,* 555 F.3d 383, 388-89 (5th Cir. 2009) (expert opinion based on erroneous or insufficient information is unreliable and

properly excluded); *Seatrax, Inc. v. Sonbeck Int'l, Inc.*, 200 F.3d 358, 371-72 (5th Cir. 2000) (affirming exclusion of expert testimony on defendant's profits by witness who failed to independently examine sales data).

Third, Dr. Kurzer does not identify or apply any principle or method that a qualified expert would employ to determine what claims Defendants made in promoting EHT and EHT products. As trier of fact in this matter, the Court is fully capable of reviewing Defendants' advertising and marketing materials on its own. To be helpful and admissible under Rule 702, expert testimony must include specialized knowledge and methods rather than naked assertions. *See Paz*, 555 F.3d at 388. Dr. Kurzer's testimony does not clear this bar.

Fourth, Dr. Kurzer lacks the necessary qualifications to offer expert opinion on whether Defendants made the challenged claims. She admits to having no expertise in advertising or marketing, App. 27-28 (Kurzer Dep. 25:17 to 26:8), which makes her unqualified to opine as an expert on what claims Defendants made in their advertising and marketing of EHT and EHT products. *See Wilson*, 163 F.3d at 937 (expert must be "qualified to testify in a particular field or on a given subject"). This alone, or in combination with the defects discussed above, makes Dr. Kurzer's testimony inadmissible under Rule 702 and *Daubert*.

C. Dr. Kurzer's opinions on FDA rules and unchallenged claims are irrelevant.

Dr. Kurzer's opinions about FDA rules and unchallenged claims are also inadmissible because they are irrelevant to this case. FTC MSJ App. 1365-78 (Kurzer Report §§ IV, V & XI). To begin with, the FTC has alleged that Defendants violated the FTC Act, not FDA rules. FDA rules are simply not implicated, so Dr. Kurzer's opinions should be excluded as not relevant. *See, e.g.*, *FTC v. Wellness Support Network, Inc.*, No. 10-cv-04879-JCS, 2013 WL 5513332, at *10 (N.D. Cal. Oct. 4, 2013) (excluding expert testimony due to expert's reliance on FDA regulations

in a case brought under the FTC Act); *Nucor Corp. v. Requenez*, 2022 WL 36095, at *8-9 (S.D. Tex. 2022) (excluding expert witnesses who evaluated allegedly defective products with a different set of standards than the one at issue).

Additionally, Dr. Kurzer's discussion of FDA rules is needlessly confusing and cannot be helpful to the Court in this action. Although difficult to follow, Dr. Kurzer's opinion traces the following path: as discussed above, she assumes (incorrectly) that Defendants did not make any disease claims about EHT and EHT products, but rather made only general health claims. She then opines that, to substantiate such general health claims about dietary supplements, the FDA does not require tests of the exact product or one very similar, or randomized clinical trials. Thus, she concludes, Defendants' substantiation of their claims complies with FDA rules. *See* FTC MSJ App. 1365-68 (Kurzer Report §§ IV.A & B). Dr. Kurzer's report therefore makes sense only if one inserts the word "legal" in front of the word "claims": she purports to opine that, for example, tests of the specific product being sold are "absolutely *not* necessary for dietary supplement health claims," FTC MSJ App. 1367 (Kurzer Report § IV.A.2.d), but what she means is that they are not necessary for *legal* dietary supplement health claims. *See* App. 34-35, 45-47 (Kurzer Dep. 32:7 to 33:20, 43:9 to 45:12). Her reasoning is thus circular: assuming Defendants have made only claims for which FDA rules require no rigorous testing, then FDA rules do not require rigorous testing to substantiate those claims. If nothing else, this part of Dr. Kurzer's report makes clear that, for *Daubert* purposes, her opinions about FDA rules are inadmissible for three independent reasons: (1) FDA rules are irrelevant because Defendants are charged with violating the FTC Act; (2) Dr. Kurzer is expressing legal opinions not permitted under Rule 702; and (3) Dr. Kurzer's opinions are unreliable because they depend entirely on her inadmissible opinion that Defendants never made the challenged claims.

Finally, Dr. Kurzer's opinions about various product claims that the FTC has *not* challenged in this case are irrelevant and therefore inadmissible. This lengthy section of her report, FTC MSJ App. 1368-78 (Kurzer Report §§ V & XI), is irrelevant because it ignores Defendants' claims that EHT or EHT Products are effective at preventing, reducing the risk of, or treating concussions, CTE, Alzheimer's, or Parkinson's, and that such effects are backed by scientific proof, as alleged in Counts III and IV of the FTC's Complaint. Because Dr. Kurzer's opinions on other claims are irrelevant and will not assist the trier of fact, her opinions should be excluded. "'Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.'" *Moore*, 151 F.3d at 275 (quoting *Daubert*, 509 U.S. at 591); *see also Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 245 (5th Cir. 2002) (excluding expert testimony for not being "relevant to the issue" before the court and thus, "not helpful to the fact-finder"); *Wellness Support Network*, 2014 WL 644749, at *9 (expert opinion that "did not address the claims that are the subject of the FTC's causes of action" excluded under Rule 702 and *Daubert*).

IV. Conclusion

For the foregoing reasons, the FTC respectfully requests that the Court exclude the expert testimony of Dr. Mindy S. Kurzer in its entirety.

Respectfully Submitted,

Dated: July 29, 2022

/s/ *Guy G. Ward*

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CERTIFICATE OF CONFERENCE

Pursuant to Federal Rule of Civil Procedure 37(a)(1) and Local Rule 7.1(a), the FTC certifies that its counsel conferred with Defendants' counsel by email on July 26, 2022, and July 28, 2022, in a good-faith effort to resolve disputes over the admissibility of expert testimony of Dr. Mindy S. Kurzer. Despite their efforts, the parties were not able to resolve the dispute. Defendants oppose this motion.

/s/ *Guy G. Ward*
GUY G. WARD